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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,889	03/25/2004	Francois Clerc	ST01027US CNT	7466

5487 7590 02/18/2005  
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EXAMINER

LEE, SUSANNAH E

ART UNIT PAPER NUMBER

1626

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/808,889	CLERC ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susannah Lee	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/21/04</u> .   | 6) <input type="checkbox"/> Other: ____                                     |

### DETAILED ACTION

Claims 1-18 are pending in the instant application.

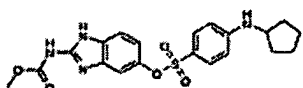
#### *Priority*

This application is a CON of PCT/EP02/11353, filed on 09/26/2002.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. EPO1402460.8 filed in the European Patent Office on 09/26/2001, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

#### *Election/Restrictions*

Applicant's election with traverse of Group I in the reply filed on 01/27/2005 is acknowledged. Specially, the election of species of the compound of Claim 7, p. 146, line 24,

and Example 19 of the specification, p. 52, lines 18-20, , Methyl-5-(4-cyclopentylaminophenylsulfonyloxy) benzimidazole-2-carbamate, is acknowledged.

The traversal is on the following grounds: (1) that a serious burden has not been placed on Examiner to require restriction, (2) that there was no lack of unity on PCT Application No. PCT/EP02/11353, (3) that the product and process of using claims should be rejoined, and (4) that the instant restriction requirement imposes both undue expenses and discourages applicants by requiring applicants to prosecute and maintain a plurality of patents.

The first reason for traversal is that a serious burden has not been placed on Examiner to require restriction. Examiner respectfully disagrees because the compounds of formula (I) are vast (various subclasses of class 544, 546, and 548) and to search all of them would impose a

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serious burden on examiner. The following were the original groups examiner made in the restriction requirement dated 12/30/2004:

Group I: Claims 1-17 drawn to products of formula (I) wherein R1 contains a cyclopentyl group as shown in claim 7, page 146, line 24, A is an aminophenyl group, and R2 is a carbamate.

Group II: Claims 1-17 drawn to products of formula (I) wherein R1 contains a morpholine group as shown in claim 11, page 151, line 15, A is an aminophenyl group, and R2 is an ester.

Group III: Claims 1-17 drawn to products of formula (I) wherein R1 contains a piperidine group as shown in claim 11, page 151, line 17, A is an aminophenyl group, and R2 is an ester.

Group IV: Claim 18 is drawn to a method of treating cancer by administering to a subject in need of treatment a compound of formula (I) according to claim 1.

The classifications and reasons for the difference in the groups are as follows. Group I is drawn to compounds of various subclasses of class 548 and the example listed is in subclass 309.1. Group II is drawn to compounds of various subclasses of class 544 and the example listed is in subclass 116. Group III is drawn to compounds of various subclasses of class 546 and the example listed is in subclass 199.

**Examiner maintains that where an election of any one of Groups I-III is made, an election of a single compound is further required** including an exact definition of each substitution on the base molecule (Formula (I)), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl and each subsequent variable position. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive

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concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.)

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

***Rationale Establishing Patentable Distinctiveness Within Each Group***

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are

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patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

***The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:***

The inventions of Groups I (class 548), Group II (class 544), and Group III (class 546) represent separate and distinct products. They differ with respect to ingredients, method steps and final result. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed in Group I can be practiced with another materially different product such as a product from Group II or Group III as showing in claims.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed in Group II can be practiced with another materially different product such as a product from Group I or Group III as showing in claims.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed in Group III can be practiced with another materially different product such as a product from Group I or Group II as showing in claims.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

The second reason for traversal is that there was no lack of unity on PCT Application No. PCT/EP02/11353. Examiner withdraws the lack of unity requirement.

The third reason for traversal is that the product and process of using claims should be rejoined at this point in the examination process.

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A)

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elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an allowed product claim**. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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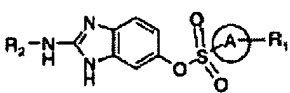
The fourth reason for traversal is that the instant restriction requirement imposes both undue expenses and discourages applicants by requiring applicants to prosecute and maintain a plurality of patents. It is not the intent of the Examiner to impose undue expenses and discourage applicants. The requirement for restriction is required because it imposes a serious burden on the Examiner to search and examine all of the above listed compounds and classes.

Therefore, for the above reasons, the requirement is still deemed proper and is therefore made FINAL.

***Scope of the Elected Invention***

Claims 1-18 are pending in this application. Claim 18 is withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the elected subject matter that will be examined and searched is as follows:

Compounds of formula (I), , depicted in claim 1, page 143, line

3, wherein:

**A** is aryl;

**R1** is one or more groups selected from:

NH2;

NH-alkyl or NH-cycloalkyl optionally substituted by acyl, acyl derivative, hydroxyl, amino, alkoxy, or aryl;

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**R2** is:

-CO-alkyl or -CO-cycloalkyl wherein said -CO-alkyl or -CO-cycloalkyl is optionally substituted by one or more amino, acyl, acyl derivative, alkoxy, aryl, OH, aminoalkyl, aminoalkylamino, hydroxyalkoxy, alkyl, arylalkyl, arylamino or aryloxy;

-CO-aralkyl optionally substituted by one or more similar or different groups selected from alkoxy, halogen, amino, acyl, acyl derivative, alkyl, hydroxyalkyl, mono or dialkylamino, arylamino, nitro, perfluoroalkyl, perfluoroalkoxy, perfluoroalkylthio, or alkylthio optionally substituted by amino, acyl derivative, alkyl, arylalkyl or aryl;

-CO-aryl optionally substituted by one or more similar or different groups selected from halogen, alkoxy, alkyl, hydroxyalkyl, alkylthio, amino, mono or dialkylamino, nitro, perfluoroalkyl, perfluoroalkoxy, perfluoroalkylthio, or acyl;

-CO-alkoxy optionally substituted by aryl, amino, acyl, acyl derivative, alkyl, arylalkyl or aryl;

-CO-amino, -CO-NHR<sub>3</sub>, -CO-NR<sub>3</sub>R<sub>4</sub> wherein R<sub>3</sub> and R<sub>4</sub> are selected independently from hydrogen, alkyl, hydroxyalkyl, alkoxyalkyl, fluoroalkyl, alkynyl, aryl, aralkyl, or together form an alkylene chain optionally substituted by one or more amino, aminoalkyl, aminoalkylamino, hydroxyl, alkoxy, hydroxyalkoxy, acyl, acyl derivative, alkyl, arylalkyl, arylamino, aryloxy or aryl; or

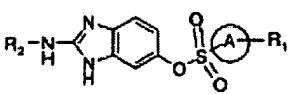
aryl or aralkyl optionally substituted by one or more similar or different groups selected from alkyl, aryl, alkoxy, amino, fluoroalkyl, acyl derivative, halogen, hydroxyalkyl, mono or dialkylamino, arylamino, nitro, perfluoroalkyl, perfluoroalkoxy, perfluoroalkylthio, or alkylthio optionally substituted by amino, acyl, acyl derivative, alkyl, arylalkyl or aryl;

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wherein when A is phenyl and R1 is NH<sub>2</sub>, NH-alkyl, NH-cycloalkyl, said phenyl is substituted at the 4-position with said R1.

***Scope of Withdrawn Subject Matter***

The scope of the withdrawn subject matter that will not be examined and searched is as follows:

Compounds of formula (I), , depicted in claim 1, page 143, line

3, wherein:

**A** is heteroaryl;

**R1** is one or more groups selected from:

alkyl optionally substituted by one or more alkoxy, heteroalkyl, aryl, acyl, acyl derivative, halogen, amino, aminoalkyl, aminoalkylamino, hydroxy, hydroxyalkoxy, alkyl, arylalkyl, arylamino or aryloxy;

alkoxy optionally substituted by one or more alkyl, heteroalkyl, aryl, heteroaryl, alkoxyalkyl, hydroxyalkyl, amide, amino, acyl, acyl derivative, arylalkyl, perfluoroalkoxy, or alkylthio optionally substituted by amide, perfluoroalkylthio, amino, acyl, acyl derivative, alkyl, arylalkyl or aryl;

aryl or heteroaryl optionally substituted by one or more similar or different groups selected from alkyl, alkoxy, nitro, cyano, acyl derivative, perfluoroalkoxy, perfluoroalkyl, heteroaryl, aryloxy, halogen, hydroxyalkyl, amino, mono or dialkylamino, heterocyclamino, arylamino, heteroarylamino, heterocycloalkyl, perfluoroalkylthio, or alkylthio optionally substituted by amino, acyl, acyl derivative, alkyl, arylalkyl or aryl;

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halogen;

1-imidazolyl; or

NH-alkyl or NH-cycloalkyl optionally substituted by heterocyclyl;

SO<sub>2</sub>Me;

**R<sub>2</sub>** is:

-CO-alkyl or -CO-cycloalkyl wherein said -CO-alkyl or -CO-cycloalkyl is optionally substituted by one or more heteroalkyl;

-CO-aralkyl optionally substituted by one or more similar or different groups selected from heterocyclylamino, heteroaryl, or heterocycloalkyl;

-CO-aryl optionally substituted by one or more similar or different groups selected from heteroaryl, or heterocycloalkyl;

-CO-amino, -CO-NHR<sub>3</sub>, -CO-NR<sub>3</sub>R<sub>4</sub> wherein R<sub>3</sub> and R<sub>4</sub> are selected independently from heteroalkyl, alkylheteroalkyl, or together form an alkylene chain optionally containing one to 4 heteroatoms; or

aryl or aralkyl optionally substituted by one or more similar or different groups selected from heterocycloalkyl, heterocyclylamino, heteroaryl, or heterocycloalkyl; wherein when A is phenyl and R<sub>1</sub> is imidazolyl, said phenyl is substituted at the 4-position with said R<sub>1</sub>; and when A is phenyl and R<sub>1</sub> is SO<sub>2</sub>Me said phenyl is substituted at the 3-position with said R<sub>1</sub>;

with the proviso that when R<sub>2</sub> is -CO-alkoxy, R<sub>1</sub> is NH-cycloalkyl, or a pharmaceutically acceptable salt or a prodrug thereof.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Loewe, et al (U.S. Pat. No. 3,996,368 (1976)).

Applicants claims of substituted benzimidazole compounds relate to compound of Formula (I) in claim 1. Loewe discloses compounds in claim 1 that anticipate the instantly claimed genus wherein: **A** is phenyl, **R1** is halogen, **R2** is a -CO-alkoxy (see Loewe et al., formula of claim 1, column 16, line 25, CAS RN 59206-73-4, 2-[(methoxycarbonyl)amino]-1H-benzimidazol-5-yl ester benzenesulfonic acid), which reads on the instant claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms “optionally substituted,” “hetero,” “heteroalkyl,” “heteroaryl,” “heterocyclylamino,” “heteroarylamino,” “heterocycloalkyl,” “heterocyclyl,” “heteroatoms,” and “prodrug” are not

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defined in the specification, claims or drawings. Applicant is invited to point out where in the original specification, claims or drawings the terms are defined. If a proper definition cannot be found, then applicant may obviate this rejection by deleting the term "optionally substituted," "hetero," "heteroalkyl," "heteroaryl," "heterocyclylamino," "heteroarylamino," "heterocycloalkyl," "heterocyclyl," "heteroatoms," and "prodrug" from the claims.

### ***Objections***

Claims 6, 8, 10, 12, 13, 15, and 17 are objected to as being dependent upon a rejected base claim.

The substituent "R2" of claim 1, page 145, line 6 is objected to because of the following minor error. The following is a suggestion to amend the claim:

The phrase "with the proviso that" be replaced by "wherein".

Claims 7, 9 (in part), 11 (in part), 14 (in part), and 16 (in part) are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. The closest prior art of record, Loewe et al., etc..., teach substituted benzimidazole compounds wherein the group corresponding to R1 are hydrogen, hydroxyl, alkoxy, halogen, trifluoromethyl, alkyl, cyano, etc... instead of an amino group like in the instant application. The instant compounds are patentable over Loewe et al. because Loewe does not teach that R1 can be a NH<sub>2</sub>, NH-alkyl, or NH-cycloalkyl group.

### ***Telephone Inquiry***

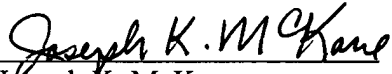
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Lee whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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